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Chapter 8

A Combination of EGb 761 and Soft Laser Therapy in Chronic Tinnitus

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/61740

Abstract

Objective: We aimed to verify the therapeutic effect of soft laser in a combination with Ginkgo biloba extract EGb 761 in patients suffering from chronic tinnitus.

Background data: Tinnitus is described as an illusory sound perceived by the patient when there is no corresponding source of this sound outside. Tinnitus may signify a disturbance of peripheral or central part of hearing system. Beside the hearing system, there might be an utterly different etiology of tinnitus. Cardiovascular, musculoskeletal, mental, and other disorders can contribute to tinnitus formation as well. Due to these multiple etiologic factors the treatment is very difficult.

Studies analyzing biological effects of EGb 761 and laser suggest their use in tinnitus treatment. However, clinical study results are very variable, which makes their general use more controversial.

Methods: We conducted a simple prospective study including 420 patients suffering from chronic tinnitus (duration 3 months to 40 years; 7.7 years mean value; SD 7.8). A soft laser BTL-10 type was used with an 830 nm / 200 mV probe, at an energy density of 50 J/cm^2, applied with transmastoidal and transmeatal approach in a continuous and pulse beam, after 3 weeks of oral use of EGb 761. The therapeutic effect was evaluated by tinnitus intensity and frequency determination (tinnitus masking) and by the subjective rating on visual analogue scale (VAS) with 0 - 10 points.

Results: Among the 420 patients, 238 (56, 7%) achieved improvement in the tinnitus masking, the average improvement in terms of intensity was found to be 30dB. Hundred and ninety-six patients (46, 7%) recorded improvement on VAS. The objective and subjective evaluation coincided in 79% of cases.

Conclusion: Compared to the outcomes of other studies, our findings reveal a relatively higher percentage of positive changes regarding the tinnitus status and greater congruence of objective (audiometric) and subjective (VAS) results.

Keywords: Tinnitus, EGb 761, laser

1. Introduction

Tinnitus is described as an illusory sound perceived by the patient when there is no corresponding source of this sound outside. Tinnitus is present in 5 - 15% of the population and in 70% of patients with hearing disturbances. Tinnitus may signify a disturbance of the peripheral or central part of the hearing system. Beside the hearing system, there are more possible causes of tinnitus - cardiovascular, musculoskeletal, metabolic, and endocrine dysfunctions (dyslipidemia, thyroid dysfunction, diabetes mellitus), and stress and mental disorders might contribute to tinnitus formation as well. Despite the diagnostic tools we have (audiometry, tinnitus masking), the exact cause often remains unrevealed. Various origins of tinnitus make the treatment very difficult and challenging as well, knowing that tinnitus itself can cause another mental and social troubles.

There are numerous chronic tinnitus treatment methods such as pharmacotherapy, physiotherapy, psychotherapy, surgery, etc., which concentrate on the tinnitus intensity reduction and patient's life quality enhancement. Unfortunately, the therapy effect is quite poor in the majority of cases, so alternative modalities of treatment are often introduced. [1] In chronic tinnitus patients, complete disparition of tinnitus arrives very rarely. The number of completely cured patients is not statistically significant.

The therapy is targeted to reducing the tinnitus sensation. We evaluate subjective feelings concerning annoyance and loudness of tinnitus described by means of visual analogue scale (VAS 0-10) and objective measurements of the frequency and intensity of tinnitus.

For better tinnitus control, a combination of treatment methods were inducted. The dual approach of Ginkgo biloba extract (EGb 761) and soft laser therapy belongs to various combined methods.

EGb 761 is a standardized extract containing 24% flavonoids, 7% proanthocyanidins, and 6% terpenoids. [2] It has a polymodal effect on the cell and tissue metabolism. The flavonoids are mainly responsible for antioxidant actions while diminishing the free radical damage. [3, 4, 5, 6] The terpenoid fraction contains Ginkolide B which is a potent platelet-activating factor (PAF) receptor antagonist. [7] EGb 761 is also a vasodilator. For hundreds of years the Ginkgo biloba extract was used for the treatment of respiratory disorders. [8] Some studies deny the therapeutic effect of Egb 761 in tinnitus, [2] while others encourage its use. [9]

Laser devices generate electromagnetic radiation with only one wave length. In the biological tissue, the laser light beams exert analgesic, anti-inflammatory, stimulation, thermal, and

http://dx.doi.org/10.5772/61740

photochemical effect. The concentrated radiation reduces the irritability of the peripheral nervous system, activates polymorphous cells, monocytes, granulocytes, and fibroblasts, activates respiration chain enzymes, and amplifies anti-oxidative effects in the mitochondria. The laser radiation intensifies metabolism in targeted tissues and cells. They gain additional energy, they can regenerate faster, and their mechanisms of protection are amplified. [10]

In the field of otoneurology, the red light spectrum lasers are the optimal. Thus, the effect we expect is mainly founded on the support of cellular oxidative processes and cell metabolism stimulation.

For the treatment of tinnitus, low level laser therapy (soft laser therapy) has been used since the early 1990s'. Studies concerning the evaluation of its therapeutic possibilities and achievements followed soon after. For both single therapy by the soft laser [11, 12, 13] and combined therapy by the soft laser with EGb 761, the results have been discouraging. [14] However, recent researches show more promising results. [15, 16, 17, 18, 19, 20] This mismatch of findings can be clarified by different researchers' approaches, which concern the design of the study, physical parameters of the laser beam, topography of the radiated region, and duration and schedule of the laser therapy. Results from more recent surveys [16, 17] are validated and confirmed by functional magnetic resonance and dosimetric studies.

This study follows our former publication, [21] whereas now involving more patients.

2. Materials and methods

At our ENT Clinic of the Third Medical Faculty, Charles University in Prague, we conducted a simple prospective study including 420 patients with chronic maskable tinnitus between years 1998 and 2006. Two hundred women and 220 men were enrolled, and the mean age of patients was 53.7 years (16 - 77 years). The onset of tinnitus was 3 months to 40 years (mean time of onset 7.7 years) (Table 1).

420 patients (200 women and 220 men)		
Age	– group:	16–77 years (53.7 mean; SD = 14.2)
	– women:	16–77 years (54.1 mean; SD = 14.1)
	– men:	16–77 years (53.3 mean; SD = 14.2)
Tinnitus duration	– group:	0.25–40 years (7.7 mean; SD = 7.8)
	– women:	0.50–32 years (7.8 mean; SD = 7.9)
	– men:	0.25–40 years (7.6 mean; SD = 7.7)

Table 1. Study cohort, demography

In the exclusion criteria otosclerosis, vestibular neurinoma, acute labyrinthine disease, serius cervical spine disorders, and serious or non-compensated metabolic disorders were comprehended.

According to the flow chart of the study, we performed thorough history taking, complex ENT examination, audiologic tests (pure tone audiometry, speech audiometry, if necessary objective audiometry as well), tinnitus intensity (dB), and frequency (Hz) determination. The subjective loudness sensation and annoyance were also recorded on visual analogue scale (0-10 points).

Three weeks before the laser therapy started, patients were instructed to take EGb 761 commercial preparations (Tanakan 80 mg or Tebokan 80 mg, in the form of tablet or drops), three times a day by peroral route of administration. The soft laser therapy followed, using BTL-10 laser device. Patients were scheduled for 10 sessions of laser therapy in at least three weeks, each session lasting 10 minutes. The parameters of the probe were adjusted for 830 nm/200 mV, at an energy density 50 J/cm^2. Initially a continuous beam followed by the pulse beam were applied, while the probe was targeted to the mastoid process and external auditory canal (aiming to cochlea).

3. Results

As to evaluate the changes of tinnitus, both subjective and objective methods were employed: tinnitus intensity and frequency determination (tinnitus masking) and rating on visual analogue scale (VAS). According to VAS, at least one point less was considered as an improvement.

In terms of audiometric changes, the average intensity improvement was found to be 30 dB (range 10-50 dB). One patient described complete disappearance of tinnitus, and one patient noted worsening of his tinnitus by 10 dB. Tinnitus intensity improved by 10 dB in 31 patients, by 20 dB in 73 patients, by 30 dB in 48 patients, by 40 dB in 38 patients, and eventually by 50 dB in 48 patients. The total number of improved cases equals to 238 (Table 2).

Change	Count	%
by 10 dB	31	13.0
by 20 dB	73	30.6
by 30 dB	48	20.2
by 40 dB	38	16.0
by 50 dB	48	20.2
∑	238	100.0

Table 2. Objective changes in tinnitus masking

Two hundred and thirty-eight cases (56.7 %) achieved improvement in the tinnitus masking, and in 182 cases (43, 7 %) tinnitus masking remained the same. Subjective relief from tinnitus, recorded by VAS questionnaire, was noted in 196 cases (46.7 %) (Table 3). An interesting observation was made in one female patient with objective improvement of 50 dB and no subjective relief from tinnitus.

http://dx.doi.org/10.5772/61740

Objective parameters		
Audiogram confirming improvement	238 patients	56.7%
Audiogram with no change	182 patients	43.3%
Subjective improvement	196 patients	46.7%

Table 3. Improvement rate

The correlation of subjective and objective measurements was following: in 79% of findings total accord was found (conformity of audiogram and VAS questionnaire), in 11% of cases no subjective improvement was reported in patients with objective audiometrical improvement, and in the remaining 10% of cases, subjective relief from tinnitus was not supported by any objective finding in audiogram (Table 4).

Correlation	**Number of patients**	**%**
Conformance of audiogram and VAS	332	79
Audiogram improvement, no VAS change	46	11
VAS improvement, no audiogram change	42	10
∑	420	100

Table 4. Correlation of subjective and objective evaluation

4. Discussion

For the tinnitus evaluation, we can never rely solely on the objective measurement tools. Many relevant factors cannot be measured, but only perceived by the patients. Tinnitus is a very subjective sound sensation, and each person feels it in his own individual way. Hence, the subjective assessment is for us as significant as objective audiometric tests. In our study, regardless the audiometric results, 46.7% of patients described a certain level of relief. The objective tests revealed that an even higher number - 56.7% - of patients displayed improvement with a relatively high mean value of 30dB. Audiometric intensity determination approved the patients' subjective records in 79% of cases, which indicates the relevance of both methods.

The study results are in accord with our everyday experience, when tinnitus intensity determination (tinnitus masking) changes are not always perceived the same way by the patient. In our study cohort 10% of patients reported diminished tinnitus perception, although the audiometric tests showed no change. This might be explicated by the placebo effect. Contrariwise, 11% of the cases were not aware of their "audiologic improvement," which is a routinely described phenomenon of central processing or imprinting of tinnitus. [22, 23]

The therapy was supported well, no serious adverse events were reported, but some patients complained of the laser's thermal effect though.

In comparison to other researches concentrating on soft laser therapy in chronic tinnitus, Shiomi et al. [11] conducted a similar design study but with no premedication by EGb 761.

Finally, he declared similar results in chronic tinnitus patients as we did. In a double-blind randomized study of Gungor et al. [18] who also used laser therapy alone (power of 5 mW, 650 nm wavelength, 15 minutes for one session), the results were similar as in our study. However, Rogowski et al. [13] and Partheniadis-Stumpf et al. [14] found out rather negative outcomes. Such a difference could be explained by different laser parameters and different number of patients in study groups. Compared to the German study, [14] we applied Egb 761 perorally three weeks before the laser therapy, expecting accentuation of the nootropic effect with a longer time of administration, while Partheniadis-Stumpf et al. [14] applied Egb 761 intravenously directly before each laser session.

5. Conclusion

Patients suffering from chronic tinnitus often try numerous therapeutic modalities in a search for alleviation of the stress and annoyance caused by their illness. According to our study results, a combination of Egb 761 and soft laser therapy can be recommended as a safe and suitable modality in the treatment of chronic maskable tinnitus.

6. Disclosure statement

This manuscript has never been submitted for a publication. It is related to, and might be considered as an extension of a previous work, which has been published as:

Hahn, A., Schalek, P., Šejna, I., Rosina, J. (2012). Combined tinnitus therapy with laser and EGb 761: further experiences. Int. Tinnitus J. 17 (1), 50-53

The authors deny any possible conflict of interest related to individual authors' commitments, project support or financial relationships of the authors.

"No competing financial interests exist."

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http://dx.doi.org/10.5772/61740

References

[1] Meehan, T., Eisenhut, M., Stephens, D. (2004). A review of alternative treatments for tinnitus. Audiol Med. 2, 74–82.

[2] Smith, P.F., Yiwen Zheng, Darlington, C. L. (2005). Ginkgo biloba extracts for tinnitus: More hype than hope? J Ethnopharmacol, 100, 1–2, 95–99.

[3] Maitra, I., Marcocci, L., Droy-Lefax, M.L., Packer, L. (1995). Peroxyl radical scavenging activity of Ginkgo biloba Extract KGB 761. Biochem Pharm. 49, 1649-1655.

[4] Pincemail, J., Deby, C. (1986). Properrietes antiradicalaires de l'extrait de Ginkgo biloba. Presse Med. 15, 1475-1479.

[5] Artmann, G.M., Schikarski, C. (1993). Ginkgo biloba Extract (EGb 761) protects red blood cells from oxidative damage. Clin. Hemorheol. 74-82.

[6] Kose, K., Dogan, P. (1995). Comparison of the antioxidant effect of the Ginkgo biloba extract (EGb 761) with those of water-soluble and lipid-soluble antioxidants. J Int Med Res. 23, 9-18.

[7] Braquet, P.G., Spinnewyn, B., Braquet, M. et al. (1985). BN 52021 and related compounds a new series of highly specific PAF-acether antagonists isolated from Ginkgo biloba. Blood Vessels 16, 558-572.

[8] Kleijnen, J., Knipschild, P. (1992). Ginkgo biloba. Lancet 340, 1136-1139.

[9] Schneider, D., Schneider, L., Shulman, A., Claussen, C.F., Just, E., Koltchev, C., Kersebaum, M., Dehler, R., Goldstein, B., Claussen, E., (2000) Ginkgo biloba (Rokan) therapy in tinnitus patients and measurable interactions between tinnitus and vestibular disturbances. Int Tinnitus J. 6, 56–62.

[10] Chomete, G., Auriol, M., Zeitoun, R. (1987). Effect of the soft laser on gingival tissue. I-Effect on fibroblasts. Histoenzymology and electron microscopy study. J Biol Buccale 15(1), 45-49.

[11] Shiomi. Y., Takahashi, H., Honjo, I. et al. (1997). Efficacy of transmeatal low power laser irradiation on tinnitus: a preliminary report. Auris Nasus Larynx 24(1), 39-42.

[12] Mirz, F., Zachariae, R., Andersen, S.E., Nielsen, S.E. et al. (1999). The low-power laser in the treatment of tinnitus. Clin Otolaryngol. 24(4), 346-354.

[13] Rogowski, M., Mnich, S., Gindzienska, E. et al. (1999). Low power laser in the treatment of tinnitus-a placebo-controlled study. Otolaryngol Pol. 53(3), 315-320.

[14] Partheniadis-Stumpf, M., Maurer, J., Mann, W. (1993). Soft laser therapy in combination with tebonin i.v. in tinnitus. Laryngorhinootologie 72(1), 28-31.

[15] Tauber, S., Baumgartner, R., Schorn, K., Beyer, W. (2001). Lightdosimetric quantitative analysis of the human petrous bone: experimental study for laser irradiation of the cochlea. Lasers Surg Med. 28(1), 18-26.

[16] Tauber, S., Schorn, K., Beyer, W., Baumgartner, R. (2003). Transmeatal cochlear laser (TCL) treatment of cochlear dysfunction: a feasibility study for chronic tinnitus. Lasers Med Sci. 18(3), 154-161.

[17] Siedentopf, C.M., Ischebeck, A., Haala, I.A. et al. (2007). Neural correlates of transmeatal cochlear laser (TCL) stimulation in healthy human subjects. Neurosci. Lett. 411(3), 189-193.

[18] Gungor, A., Dogru, S., Cincik, H., Erkul, E., Poyrazoglu, E. (2007). Effectiveness of transmeatal low power laser irradiation for chronic tinnitus. J Laryngol Otol. 12, 1-5.

[19] Salahaldin, A. H., Abdulhadi, K., Najjar, N., Bener, A. (2012). Low-level laser therapy in patients with complaints of tinnitus: a clinical study. ISRN, Otolaryngol, Article ID 132060.

[20] Okhovat, A., Nezamoddin, B., Okhovat, H., Malekpour, A., Abtahi, H. (2011). Low-level laser for treatment of tinnitus: a self-controlled clinical trial. J Res Med Sci 16(1), 33-38.

[21] Hahn, A., Schalek, P., Šejna, I., Rosina, J. (2012). Combined tinnitus therapy with laser and EGb 761: further experiences. Int Tinnitus J. 17(1), 50-53.

[22] Shulman, A., Goldstein, B. (2006). Tinnitus dyssynchrony-synchrony theory: a translational concept for diagnosis and treatment. Int Tinnitus J. 12(2), 101-114.

[23] Jastreboff, P.J., Hazell, J.W.P. (1993). A neurophysiological approach to tinnitus: clinical implications. Br J Audiol. 27, 7-17.